July 3, 2025

WONTECH Co., Ltd.
Hyun Yoon
Team Leader
64 Techono 8-ro, Yuseong-gu
Daejeon, 34028
Korea, South

Re: K250165
Trade/Device Name: Pastelle
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: June 5, 2025
Received: June 5, 2025

Dear Hyun Yoon:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

MARK MACIOS -S
Digitally signed by MARK MACIOS -S
Date: 2025.07.03 09:49:40 -04'00'

for Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K250165

Device Name
Pastelle

Indications for Use *(Describe)*
The Pastelle laser system is intended for use in aesthetic, cosmetic and surgical applications requiring incision, excision, ablation, vaporization of soft tissues for general dermatology, dermatologic and general surgical procedures for coagulation and hemostasis.
1064nm in nanosecond mode, including microbeam handpieces:
- Tattoo removal: dark ink (black, blue, and brown)
- Removal of Nevus of Ota
- Removal or lightening of unwanted hair with or without adjuvant preparation
- Treatment of Common Nevi
- Skin resurfacing procedures for the treatment of acne scars and wrinkles
- Treatment of melasma

1064nm in Genesis (long-pulse) mode:
- Treatment of wrinkles
- Treatment of mild to moderate inflammatory acne vulgaris

532nm in nanosecond mode, including microbeam handpieces (nominal delivered energy of 595 nm and 660 nm with optional dye handpieces):
- Tattoo removal: light ink (red, tan, purple, orange, sky blue, green)
- Removal of Epidermal Pigmented Lesions
- Removal of Minor Vascular Lesions including but not limited to telangiectasias
- Skin resurfacing procedures for the treatment of acne scars and wrinkles
- Treatment of Lentigines
- Treatment of Café-au-Lait
- Treatment of Seborrheic Keratoses
- Treatment of Post Inflammatory Hyperpigmentation
- Treatment of Becker's Nevi, Freckles, and Nevi spilus

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

64 Techno 8-ro, Yuseong-gu, Daejeon, Republic of Korea
TEL: +82 (42) 934 6800 FAX: +82 (42) 934 9491

510(k) Summary

[As required by 21 CFR 807.92]

K250165

1. Date Prepared [21 CFR 807.92(a)(a)]

June 27, 2025

2. Submitter's Information & Contact Person [21 CFR 807.92(a)(1)]

- Name of Manufacturer: WON TECH Co., Ltd.
- Address: 64 Techno 8-ro, Yuseong-gu, Daejeon, 34028, Republic of Korea
- Contact Name: Hyun Sik Yoon
- Telephone No.: +82-10-6750-5346
- Fax No.: +82-70-7836-0110
- Email Address: yoonhs21@wtlaser.com

3. Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

Common name: Q-switched Nd:YAG Laser System
Trade name: Pastelle

Classification Description	21 CFR Section	Product Code
Powered Laser Surgical Instrument	878.4810	GEX

As stated in 21 CFR, parts 878.4810, this generic types of devices has been classified as Class II.

64 Techno 8-ro, Yuseong-gu, Daejeon, Republic of Korea
TEL: +82 (42) 934 6800 FAX: +82 (42) 934 9491

4. Identification of Predicate Device(s) [21 CFR 807.92(a)(3)]

The identified predicate devices within this submission are shown as follow:

#1 Predicate device

- 510(k) Number: K123293
- Applicant: WON TECH Co., Ltd.
- Classification Name: Powered Laser Surgical Instrument
- Trade Name: Pastelle

#2 Predicate device

- 510(k) Number: K241529
- Applicant: WON TECH Co., Ltd.
- Classification Name: Powered Laser Surgical Instrument
- Trade Name: Pastelle Pro

#3 Predicate device

- 510(k) Number: K213569
- Applicant: Lutronic Corporation
- Classification Name: Powered Laser Surgical Instrument
- Trade Name: HOLLYWOOD SPECTRA Laser System

5. Description of the Device [21 CFR 807.92(a)(4)]

The Pastelle laser system consists of an Nd:YAG laser head, a power supply, a cooling system, a delivery system and other electrical components. The laser head contains two Nd:YAG laser medium, and two high-intensity xenon flash lamps enclosed together into the water cooling housing and two reflected mirrors fixed ,in the special adjustable holders composed the laser cavity.

6. Indications for Use [21 CFR 807.92(a)(5)]

The Pastelle system is intended for use in aesthetic, cosmetic and surgical applications requiring incision, excision, ablation, vaporization of soft tissues for general dermatology, dermatologic and general surgical procedures for coagulation and hemostasis.

1064nm in nanosecond mode, including microbeam handpieces:

- Tattoo removal: dark ink (black, blue, and brown)
- Removal of Nevus of Ota
- Removal or lightening of unwanted hair with or without adjuvant preparation
- Treatment of Common Nevi

64 Techno 8-ro, Yuseong-gu, Daejeon, Republic of Korea
TEL: +82 (42) 934 6800 FAX: +82 (42) 934 9491

- Skin resurfacing procedures for the treatment of acne scars and wrinkles
- Treatment of melasma

1064nm in Genesis (long-pulse) mode:
- Treatment of wrinkles
- Treatment of mild to moderate inflammatory acne vulgaris

532nm in nanosecond mode, including microbeam handpieces (nominal delivered energy of 595 nm and 660 nm with optional dye handpieces):
- Tattoo removal: light ink (red, tan, purple, orange, sky blue, green)
- Removal of Epidermal Pigmented Lesions
- Removal of Minor Vascular Lesions including but not limited to telangiectasias
- Skin resurfacing procedures for the treatment of acne scars and wrinkles
- Treatment of Lentigines
- Treatment of Café-au-Lait
- Treatment of Seborrheic Keratoses
- Treatment of Post Inflammatory Hyperpigmentation
- Treatment of Becker's Nevi, Freckles, and Nevi spilus

64 Techno 8-ro, Yuseong-gu, Daejeon, Republic of Korea
TEL: +82 (42) 934 6800 FAX: +82 (42) 934 9491

7. Determination of Substantial Equivalence [21 CFR 807.92(a)(6) and 21 CFR 807.92(b)]

There are no significant differences between the Pastelle and the predicate devices that would adversely affect the use of the product. It is substantially equivalent to this device in design, function, and technical characteristics.

	Proposed Device	Predicate Device #1	Predicate Device #2	Predicate Device #3	SE Decision
K Number	-	K123293	K241529	K213569	-
Manufacturer	WONTECH Co., Ltd.	WONTECH Co., Ltd.	WONTECH Co., Ltd.	Lutronic Corporation	-
Model	Pastelle	Pastelle	Pastelle Pro	HOLLYWOOD SPECTRA Laser System	-
Product Code	GEX	GEX	GEX	GEX	**Same**
Intended Use	The Pastelle system is intended for use in aesthetic, cosmetic and surgical applications requiring incision, excision, ablation, vaporization of soft tissues for general dermatology, dermatologic and general surgical procedures for coagulation and hemostasis. 1064nm in nanosecond mode, including microbeam handpieces: - Tattoo removal: dark ink (black, blue, and brown) - Removal of Nevus of Ota - Removal or lightening of unwanted hair with or without adjuvant preparation	Pastelle Q-Switched Nd:YAG Laser System is indicated for the Incision, Excision, Ablation and Vaporization of Soft Tissue for General Dermatology, Dermatologic and General Surgical Procedures for Coagulation and Hemostasis.	The Pastelle Pro system is intended for use in aesthetic, cosmetic and surgical applications requiring incision, excision, ablation, vaporization of soft tissues for general dermatology, dermatologic and general surgical procedures for coagulation and hemostasis. 1064nm in nanosecond mode, including microbeam handpieces: - Tattoo removal: dark ink (black, blue, and brown) - Removal of Nevus of Ota - Removal or lightening of unwanted hair with or without adjuvant preparation	The HOLLYWOOD SPECTRA System is intended for use in aesthetic, cosmetic and surgical applications requiring incision, excision, ablation, vaporization of soft tissues for general dermatology, dermatological and general surgical procedures for coagulation and hemostasis. 1064nm in nanosecond mode, including microbeam handpieces: - Tattoo removal: dark ink (black, blue, and brown) - Removal of Nevus of Ota - Removal or lightening of unwanted hair with or without adjuvant preparation	**Same as Predicate Device #2 and 3**

64 Techno 8-ro, Yuseong-gu, Daejeon, Republic of Korea
TEL: +82 (42) 934 6800 FAX: +82 (42) 934 9491

	- Treatment of Common Nevi - Skin resurfacing procedures for the treatment of acne scars and wrinkles - Treatment of melasma 1064nm in Genesis (long-pulse) mode: - Treatment of wrinkles - Treatment of mild to moderate inflammatory acne vulgaris 532nm in nanosecond mode, including microbeam handpieces (nominal delivered energy of 595 nm and 660 nm with optional dye handpieces): - Tattoo removal: light ink (red, tan, purple, orange, sky blue, green) - Removal of Epidermal Pigmented Lesions - Removal of Minor Vascular Lesions including but not limited to telangiectasias - Skin resurfacing procedures for the treatment of acne scars and wrinkles - Treatment of Lentigines - Treatment of Café-au-Lait - Treatment of Seborrheic Keratoses - Treatment of Post Inflammatory Hyperpigmentation - Treatment of Becker's Nevi, Freckles, and Nevi spilus		- Treatment of Common Nevi - Skin resurfacing procedures for the treatment of acne scars and wrinkles - Treatment of melasma 1064nm in Genesis (long-pulse) mode: - Treatment of wrinkles - Treatment of mild to moderate inflammatory acne vulgaris 532nm in nanosecond mode, including microbeam handpieces (nominal delivered energy of 595 nm and 660 nm with optional dye handpieces): - Tattoo removal: light ink (red, tan, purple, orange, sky blue, green) - Removal of Epidermal Pigmented Lesions - Removal of Minor Vascular Lesions including but not limited to telangiectasias - Skin resurfacing procedures for the treatment of acne scars and wrinkles - Treatment of Lentigines - Treatment of Café-au-Lait - Treatment of Seborrheic Keratoses - Treatment of Post Inflammatory Hyperpigmentation - Treatment of Becker's Nevi,	- Treatment of Common Nevi - Skin resurfacing procedures for the treatment of acne scars and wrinkles - Treatment of melasma 1064nm in Spectra (long-pulse) mode: - Treatment of wrinkles - Treatment of mild to moderate inflammatory acne vulgaris 532nm in nanosecond mode, including microbeam handpieces (nominal delivered energy of 585 nm and 650 nm with optional dye handpieces): - Tattoo removal: light ink (red, tan, purple, orange, sky blue, green) - Removal of Epidermal Pigmented Lesions - Removal of Minor Vascular Lesions including but not limited to telangiectasias - Skin resurfacing procedures for the treatment of acne scars and wrinkles - Treatment of Lentigines - Treatment of Café-au-Lait - Treatment of Seborrheic Keratoses - Treatment of Post Inflammatory Hyperpigmentation - Treatment of Becker's Nevi, Freckles, and Nevi spilus	

			Freckles, and Nevi spilus		
Principle/Method of Operation	The Pastelle laser system consists of an Nd:YAG laser head, a power supply, a cooling system, a delivery system and other electrical components. The laser head contains two Nd:YAG laser medium, and two high-intensity xenon flash lamps enclosed together into the water cooling housing and two reflected mirrors fixed ,in the special adjustable holders composed the laser cavity.	The Pastelle laser system consists of an Nd:YAG Laser head, a Power supply and a cooling system. The laser head contains two Nd:YAG laser medium, and two high-intensity xenon flash lamps enclosed together into the water cooling housing and two reflected mirrors fixed ,in the special adjustable holders composed the laser cavity.	The Pastelle Pro laser system consists of an Nd:YAG laser head, a power supply, a cooling system, a delivery system and other electrical components. The laser head contains two Nd:YAG laser medium, and two high-intensity xenon flash lamps enclosed together into the water cooling housing and two reflected mirrors fixed ,in the special adjustable holders composed the laser cavity.	The HOLLYWOOD SPECTRA Laser System contains a Nd:YAG (Neodymium-doped Yttrium Aluminum Garnet) resonator which generates Q-switched and/or pulsed laser sources at the nominal wavelength of 1064 nm and 532 nm using KTP. The outputs of each laser generator and the aiming beam (655 nm) are delivered by articulated arm to a fixed (collimated), or focusing variable (zoom) spot handpiece, or a dual focused dots microbeam handpiece, or a 585nm/650nm dye laser converter handpiece. The dye handpieces convert the KTP 532 nm wavelength beam into a 585 nm or 650 nm wavelengths, correspondingly.	**Same as Predicate Device #1 and #2** (Q-switched, Nd:YAG)
Laser Material	Nd:YAG	Nd:YAG	Nd:YAG	Nd:YAG	**Same**

	Proposed Device	Predicate Device #1	Predicate Device #2	Predicate Device #3	SE Decision
Radiation diameter	**Zoom:** 2mm ~ 10mm **DOE:** 5mm x 5mm ~ 7mm x 7mm	**Zoom:** 2mm ~ 10mm	**Zoom:** 2mm ~ 10mm **Collimation:** 7mm **MLA:** 3mm ~ 8mm **DOE:** 5mm x 5mm ~ 7mm x 7mm **Dye:** 3mm	**1064 Zoom:** 1 ~ 7mm (Q-Switch, Spectra) / 2 ~ 7mm (Q-PTP, Q-3, Q-4) **532 Zoom:** 0.8 ~ 6mm **Collimation:** 3 ~ 8mm **MDF:** 1064(4~8mm) / 532(3.4~6.9mm)	**Same** (The range of specification of submitted device is covered by all predicate

				Dye: 2~5mm	devices' feature)
Laser output power	**Genesis mode:** 100 ~ 3,500 mJ **1064 nm mode:** 80 ~ 1,300 mJ **1064 nm PTP mode:** 80 ~ 1,600 mJ **532 nm mode:** 10 ~ 500 mJ **1064 nm DOE mode:** 80 ~ 900 mJ	**Genesis mode:** 100 ~ 2,000 mJ **1064 nm mode:** 80 ~ 1,300 mJ **532 nm mode:** 10 ~ 500 mJ	**Genesis mode:** 100 ~ 5,000 mJ **1064 nm mode:** 50 ~ 1,200 mJ **1064 nm PTP mode:** 600 ~ 2,000 mJ **1064 nm Triple mode:** 1,000 ~ 1400 mJ **1064 nm 2x PTP mode:** 1,000 ~ 1400 mJ **532 nm mode:** 30 ~ 500 mJ **1064 nm DOE mode:** 60 ~ 900 mJ **595 nm Dye mode:** 30 ~ 250 mJ	**Spectra:** Up to 1500mJ **1064nm:** Up to 1200mJ **1064nm PTP:** Up to 1400mJ **1064nm Q-3, Q-4:** Up to 1400mJ **532nm:** Up to 400mJ	**Same** (The range of specification of submitted device is covered by all predicate devices' feature)
Pulse width	**Genesis mode:** 80~480µs **PTP mode:** 4~48ns **1064, 532 mode:** 4~48ns	**Genesis mode:** 250~350µs **1064 mode:** 4~48ns **532 mode:** 4~48ns	**532nm/1064nm mode:** 5ns~12ns **1064 PTP/Triple/2X PTP:** Up to 20ns **Genesis mode:** 80~300µs	**Normal:** 5~10ns **1064 Q-3, Q-4:** 10~20ns **Spectra mode:** 190µs	**Same** (The range of specification of submitted device is covered by all predicate devices' feature)
Pulse repetition rate	**Genesis mode:** 1 ~ 10 Hz **1064 nm mode:** 1 ~ 10 Hz **1064 nm PTP mode:** 1 ~ 10 Hz **532 nm mode:** 1 ~ 10 Hz **1064 nm DOE mode:** 1 ~ 10 Hz	**Genesis mode:** 1 ~ 10 Hz **1064 nm mode:** 1 ~ 10 Hz **532 nm mode:** 1 ~ 10 Hz	**Genesis mode:** 1 ~ 10 Hz **1064 nm mode:** 1 ~ 10 Hz **1064 nm PTP mode:** 1 ~ 10 Hz **1064 nm Tripple mode:** 1 ~ 10 Hz **1064 nm 2x PTP mode:** 1 ~ 10 Hz **532 nm mode:** 1 ~ 10 Hz **1064 nm DOE mode:** 1 ~ 10 Hz **595 nm Dye mode:** 1 ~ 5 Hz **660 nm Dye mode**: 1 ~ 2 Hz	**1064, 532nm:** Up to 10Hz	**Same** (The range of specification of submitted device is covered by all predicate devices' feature)

64 Techno 8-ro, Yuseong-gu, Daejeon, Republic of Korea
TEL: +82 (42) 934 6800 FAX: +82 (42) 934 9491

Non-Clinical Test Summary [21 CFR 807.92(b)(1)]

1) Electrical Safety, Electromagnetic Compatibility Testing

Bench tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device complies with the following standards:

Standard (Edition)	Standard Title
IEC 60601-1:2005/AMD2:2020	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance — Amendment 2
IEC 60601-1-2:2014+A1:2020	Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances — Requirements and tests
IEC 60601-1-6:2010/AMD2:2020	Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral Standard: Usability — Amendment 2
IEC 60601-2-22:2019	Medical electrical equipment — Part 2-22: Particular requirements for the basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment
IEC 60825-1:2014 (Third Edition	Safety of laser products - Part 1: Equipment classification and requirements

-

2) Software Validation

The PASTELLE contains BASIC documentation level software. Software was designed and developed according to a software development process and was verified and validated.

The software information is provided in accordance with FDA guidance: The content of premarket submissions for software contained in medical devices, on May 11, 2005.

3) Biocompatibility

Part	**Material**	**Patient Contact**	**Duration of Contact by ISO 10993-1**	**Bio-compatibility**
Handpiece Tip	Aluminium Powder (Cas No. 7429-90-5)	Intact Skin	Limited (< 24 hours)	Yes

64 Techno 8-ro, Yuseong-gu, Daejeon, Republic of Korea
TEL: +82 (42) 934 6800 FAX: +82 (42) 934 9491

4) Performance Testing

The performance of the PASTELLE has been defined as follows.

Treatment Laser
• Genesis mode (1064nm): Up to 3500mJ (80μs to 480μs)
• PTP mode (1064nm): Up to 1600mJ (4ns to 48ns)
• 1064nm mode: Up to 1300mJ (4ns to 48ns)
• 532nm mode: Up to 500mJ (4ns to 48ns)

Aiming Beam
• Wavelength: 635nm
• Output power: < 5mW

Clinical Test Summary [21 CFR 807.92(b)(2)]

No clinical studies were considered necessary and performed.

Conclusion [21 CFR 807.92(b)(3)]

In according with the Federal Food & drug and cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification WON TECH Co., Ltd. concludes that the PASTELLE is substantially equivalent to predicate devices as described herein.